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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,836	04/26/2005	Armin Breitenbach	12961/46601	8861

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EXAMINER	
VALENROD, YEVGENY	
ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
06/15/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/532,836	BREITENBACH ET AL.	
	Examiner	Art Unit	
	YEVEGENY VALENROD	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 April 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-39 and 70-72* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-39 and 70-72* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *26 April 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following is a final office action in application # 10/532,836

Amendments to the claims filed 4/1/09 are acknowledged.

Remarks filed 4/1/09 have been considered by the examiner and are addressed following the text of the new and maintained rejections.

Rejection of claims 35-39 under 35 USC 102(b) over Meese et al. is withdrawn in favor of a new rejection over the same reference that accounts for the new claim limitations.

Objection to the drawings is withdrawn.

Objection to the specification for lacking a brief description of the drawing is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35-39 and 70-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejected claims are directed to a compound of formula (I), however the newly amended claims now comprise limitations

directed to a “dosing unit” which is described as a pharmaceutical formulation (page 16 lines 20-21 of the specifiation). It is not clear if the applicant is claiming a compound or a composition.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 35-39 and 70-72 are rejected under 35 U.S.C. 102(b) as being anticipated by Meese et al (WO99/58478; already of record).

Meese et al disclose R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester (page 11, lines 13-14), (the compound of the instant claim 39). The above compound is disclosed as a free base of R configuration and is inherently pure. The limitations directed to the dosing unit is inherently met by the compound of Meese et al. because the term "dosing unit” as defined in the instant specification is open to any amount of the active ingredient (page 16, lines 20-25 of the specification).

Alternatively if the applicant intends for the claims to be directed to the pharmaceutical composition, the following obviousness rejection applies.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 35-39 and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meese et al (WO99/58478; already of record).

Scope of prior art

Meese et al disclose R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester (page 11, lines 13-14), (the compound of the instant claim 39). The above compound is disclosed as a free base of R configuration. The invention of Meese et al encompasses free bases and pharmaceutical formulations of the disclosed compounds (page 6, lines 10-11 of the written text; page 35, paragraph 3).

Ascertaining the difference

Meese et al fail to provide an example where R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester is formulated into a pharmaceutical composition and also they are silent as to the purity of the compound in the said composition.

Obviousness

One skilled in the art would find it obvious to formulate the free base of R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester into a pharmaceutical composition. A pharmaceutical composition meets the limitation of

the instant claims directed to "dosing unit". It is also obvious to obtain a highly pure form of the R-(+)-isobutyric acid 2-(3-diisopropylamino-1-phenylpropyl)-4-hydroxymethylphenyl ester. Purification techniques such as chromatography are well known in the art and one skilled in the art would find it obvious to purify the compound after completing the synthetic procedure for its preparation. Expected outcome is producing a pure active ingredient free from the byproducts and additives commonly used in the synthetic procedure.

Reply to applicants' remarks

Applicants have argued that Meese fails to disclose the purity of the obtained compositions.

Examiner does not find the above argument persuasive because the applicants are claiming a compound not a composition and a single compound is inherently pure. Furthermore a synthetic product can be purified via chromatographic techniques to produce a pure compound. Doing so is routine and is commonly performed in order to properly identify the product by spectroscopic methods.

It is also obvious to produce a composition with various concentrations of the active ingredient. If applicants' intention is to claim a composition and not a compound, unexpected results arising from the purity and salt content of the said composition would be required to overcome the rejection over Meese. Furthermore, Messe does not

only name the compound as part of a specification, but also claims the compound and a method of its preparation (claims 4 and 24).

Conclusion

Claims 35-39 and 70-72 are pending

Claims 35-39 and 70-72 are rejected

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yevgeny Valenrod whose telephone number is 571-272-9049. The examiner can normally be reached on 8:30am-5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-0779. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Yevgeny Valenrod/

_____

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